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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/542,935	04/04/2000	Maria Palasis	02844 56301	5876

26646 7590 12/30/2002

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	7

DATE MAILED: 12/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/542,935	PALASIS, MARIA	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,9-12,17-20,24,26,27,30,32-39,42-44,47,50-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *2*.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4-8,13-16,21-23,25,28,29,31,40,41,45,46,48 and 49.

DETAILED ACTION

Non-Final Rejection

Claims 1, 3, 9-12, 17-20, 24, 26-27, 30, 32-39, 42-44, 47, 50-59 are pending examination.

Addition of claims 52-59 in paper no. 6 is acknowledged.

Applicant's election without traverse of species 'a non-genetic therapeutic agent"; metallic stent; angiogenic agent in Paper No. 6 is acknowledged.

Claims 2, 4-8, 13-16, 21-23, 25, 28-29, 31, 40-41, 45, 46, 48-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Claim Objections

Claims 1, 9, 26, 32-33, 39, 53, 57 are objected to because of the following informalities: claims read on non-elected species. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the limitation "said non-plasmid vector" in line 6, page 34. There is insufficient antecedent basis for this limitation in the claim. Claim 30 depends on claim 26 and claim 26 does not recite a non-plasmid vector.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 9, 10, 11, 12, 17, 19, 20, 24, 26, 32, 33, 34, 35, 36, 37, 39, 42, 44, 47, 50, 51, 52, 53, 54, 55, 56, 57, 58, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Donovan et al. (US Patent No. 5,833,651). Donovan teaches a device comprising a stent to deliver virus to the wall of a lumen for gene delivery (column 2, line 65-column 4, line 35). More specifically, the stent has a polymer composition comprising fibrin, the composition covering at least a portion of the lumen wall-contacting surface of the stent. The virus can be an adenovirus or a retrovirus and the virus is capable of expressing a protein in a cell and a

liposome can be incorporated in to the polymer-coated stent (column 10, line 35-column 11, line 67). The device can further comprise a biodegradable second polymer composition covering at least a portion of the first polymer composition on the lumen wall-contacting surface. Donovan further teaches using a different types of stents, including metal stents (column 5, line 55-column 8, line 65). The second composition can further comprise an anti-inflammatory compound. In addition, Donovan teaches a method of delivering nucleic acid to cells using the device described above (columns 20-22, claims 21-28). Furthermore, Donovan cites methods for using a spray application to cover the stent (column 10, lines 9-10).

Claims 1, 9, 10, 11, 12, 17, 19, 20, 24, 26, 30, 32, 33, 34, 35, 36, 37, 38, 42, 44, 47, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Palasis et al. (US Patent No. 6,369,039). Palasis teaches a system for delivering a therapeutic agent to a body cavity comprising a medical device (e.g. metal stent) having a saturated solution of the therapeutic agent (e.g. viral vector comprising an angiogenic factor) associated therewith (abstract, Figure 1, and column 3, line 1-column 7, line 67). The device comprises a polymer coating capable of absorbing or withholding the therapeutic agent to be delivered. Palasis further teaches using an enhancer, which helps the therapeutic agent across biological membranes (column 8, lines 37-61). Furthermore, Palasis teaches using the device in a therapeutic application including balloon angioplasty (column 7, lines 50-62).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

Claims 1, 3, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan et al. (US Patent No. 5,833,651) taken with Branellec et al. (US Patent No. 5,851,521). Donovan teaches a device comprising a stent to deliver virus to the wall of a lumen for gene delivery (column 2, line 65-column 4, line 35). More specifically, the stent has a polymer composition comprising fibrin, the composition covering at least a portion of the lumen wall-contacting surface of the stent. The virus can be an adenovirus or a retrovirus and the virus is capable of expressing a protein in a cell and a liposome can be incorporated in to the polymer-coated stent (column 10, line 35-column 11, line 67). The device can further comprise a biodegradable second polymer composition covering at least a portion of the first polymer composition on the lumen wall-contacting surface. Donovan further teaches using a different types of stents, including metal stents (column 5, line 55-column 8, line 65). The second composition can further comprise an anti-inflammatory compound. In addition, Donovan teaches a method of delivering nucleic acid to cells using the device described above (columns

20-22, claims 21-28). However, Donovan does not specifically teach using an adeno-associated viral (AAV) vector in the device or method of delivering a nucleic acid and a non-genetic agent to a cell using said device.

However, at the time the invention was made, AAV viral vectors were known for delivering nucleic acid to cells using a catheter and using micro-particles (e.g. polylactide) to deliver said nucleic acid (column 9, line 60-column, line 67). Branellec teaches using AAV vectors comprising the protein GAX in a method inhibiting restenosis in a mammal (abstract and column 7, lines 55-65). AAV vectors are able to infect a wide spectrum of cells without inducing any effect on cellular growth, morphology, or differentiation and they do not appear to be involved in human pathologies.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Donovan taken with Branellec, namely to use an recombinant AAV as the viral vector in the device taught by Donovan. One of ordinary skill in the art would have been motivated to use an AAV vector in the device because AAV vectors were well known in the art for use in gene delivery of a GAX protein to inhibit restenosis in a patient. In addition, one of ordinary skill in the art would have been motivated to use the device in a method of delivering a nucleic acid (AAV vector comprising a nucleic acid encoding and angiogenic protein) and a non-genetic agent to a cell to avoid one of the problems (targeting desired cells) associated with gene delivery to cells.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1, 18, 26, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan et al. (US Patent No. 5,833,651) taken with (Lennox, US Patent No. 6,280,411). Donovan teaches a device comprising a stent to deliver virus to the wall of a lumen for gene delivery (column 2, line 65-column 4, line 35). More specifically, the stent has a polymer composition comprising fibrin, the composition covering at least a portion of the lumen wall-contacting surface of the stent. The virus can be an adenovirus or a retrovirus and the virus is capable of expressing a protein in a cell and a liposome can be incorporated in to the polymer-coated stent (column 10, line 35-column 11, line 67). The device can further comprise a biodegradable second polymer composition covering at least a portion of the first polymer composition on the lumen wall-contacting surface. Donovan further teaches using different types of stents, including metal stents (column 5, line 55-column 8, line 65). The second composition can further comprise an anti-inflammatory compound. In addition, Donovan teaches a method of delivering nucleic acid to cells using the device described above (columns 20-22, claims 21-28). Furthermore, Donovan cites methods for using a spray application to cover the stent (column 10, lines 9-10). However, Donovan does not specifically teach a medical device, wherein the polymer coating is about 1 to about 40 layers having a thickness of about 1 to about 10 μm/layer of coating or using the medical device to deliver a nucleic acid and a non-genetic agent to a cell.

However, at the time the invention was made, Lennox teaches medical devices and methods for the controlled localized delivery of drug agents, such as nucleic acid vectors, to target locations within a mammalian body (column 2, line 35-column 3, line 24). Lennox

teaches that the device is typically coated with a polymer that is about 1 to 10 microns in thickness and multiple layers of the polymer coating.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made as routine to combine the teaching of Donovan taken with Lennox, namely to coat the device with a polymer that is about 1 to 10 microns in thickness and multiple layers of the polymer coating. One of ordinary skill in the art would have been motivated to use the conditions taught by Lennox for the coating the stent in the device because it is the typical or preferred thickness for coating the device. In addition, the claimed conditions, as evidence to the contrary, do not display an unexpected advantage as compared to using a different thickness of coating.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader, SPE - Art Unit 1635, can be reached at (703) 308-0447.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman
Patent Examiner, Group 1635
12/13/02

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER